



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20531
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,543	07/27/2001	Konrad Basler	Q-60361	9256

7590 09/19/2002

SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER

LACOURCIERE, KAREN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/19/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,543

Applicant(s)

BASLER ET AL.

Examiner

Karen Lacourciere

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-21,23-59 and 61-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,4-21,23-59 and 61-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 35-38, 40, 41, 43, 45, 46, 48, 49, 50, 66, 67 and 68, drawn to a nucleotide encoding a legless protein, classified in class 536, subclass 23.1.
- II. Claims 13-16, 20, 21, 23, 24, 44 or 63, drawn to a legless polypeptide, classified in class 530, subclass 350.
- III. Claims 17, 61, and 69, drawn to a method for isolating a legless binding protein, classified in class 435, subclass 70.1.
- IV. Claim 18, drawn to a process of making a legless protein, classified in class 435, subclass 70.1.
- V. Claims 19 and 62, drawn to an antibody targeted to a legless protein, classified in class 530, subclass 387.1.
- VI. Claims 25-29, drawn to a compound that interferes with the binding of partner proteins with a legless protein, classified in class 530, subclass 350.
- VII. Claim 30, drawn to a synthetic molecule that stimulates a legless protein, classified in class 530, subclass 350.
- VIII. Claims 32, 64 and 65, drawn to a legless antagonist, classified in class 530, subclass 350.

- IX. Claim 33, drawn to a method of screening for antagonists of legless, classified in class 435, subclass 7.1.
- X. Claims 39, 51 and 53-59, drawn to a method of treatment for a wnt related disease, classified in class 514, subclass 44.
- XI. Claim 70, drawn to a method of diagnosing a cell fate disorder, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products that are not capable of use together. For example, the oligonucleotides of Group I are composed of nucleotides and have the function of expressing a legless protein, whereas the proteins of Group II are composed of amino acids and have the function of operating in the Wnt pathway.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and a method which does not utilize the product and these inventions have different functions and effects. For example, the invention of Group I is a product which functions to encode a legless

Art Unit: 1635

polypeptide, which is not used in the method for isolating the legless binding protein of Group III, which functions to isolate a protein which binds to a legless protein.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in a materially different method of using the product, for example, the nucleic acids of Group I can be used in a diagnostic method, as a probe, to determine the expression level of legless mRNA.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products which are not capable of use together and which have different functions and different modes of operation. For example, the oligonucleotides of Group I are composed of nucleotides and function to encode a legless polypeptide, whereas the antibodies of Group V are composed of amino acids and function to bind to a legless polypeptide and increase its degradation.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

Art Unit: 1635

the instant case the different inventions are not capable of use together and have different functions. For example, the nucleotides of Group I function to encode a legless protein, whereas the compounds of Group VI function to inhibit the interaction of a legless protein with a binding partner.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to inventions that are not capable of use together and have different functions. For example, the oligonucleotides of Group I function to encode a legless polypeptide, whereas the synthetic compounds of Group VII function to stimulate the activity of a legless protein.

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to inventions that are not capable of use together and have different functions. For example, the oligonucleotides of Group I function to encode a legless polypeptide, whereas the antagonists of Group VIII function to inhibit the activity of a legless protein.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have

Art Unit: 1635

different functions. For example, the oligonucleotides of Group I function to encode a legless polypeptide, and are not used in the methods of Group IX, which function to determine antagonists of a legless protein.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotides of Group I can be used in a method of purifying a legless polypeptide, which is materially different than the methods of treatment of Group X.

Inventions I and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions, for example, the oligonucleotide is not used in the claimed methods of diagnosing of Group XI and have the function of expressing a legless protein, whereas the methods of diagnosing of Group IX have the function of determining a cell fate disorder in a subject.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

Art Unit: 1635

process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II can be used in a materially different method than the method isolating a binding protein of Group III, for example, the polypeptide of Group II can be used in a method of treatment, which is materially different than the isolation methods of Group II.

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein of Group II can be made by isolating the protein from cells, wherein the protein is expressed at natural levels, not recombinantly, which is materially different than the methods of Group IV, which require recombinant expression of the legless protein.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to compositions which have different functions and modes of operation, for example, the polypeptides of Group II function as a legless protein, whereas the antibodies of Group V function by binding to a legless protein, increasing the rate of degradation of the legless protein.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

Art Unit: 1635

the instant case the different inventions have different functions. For example, the protein of Group II functions as a legless protein in the Wnt pathway, whereas the compound of Group VI functions to interfere with a binding partner of a legless protein.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. For example, the protein of Group II functions as a legless protein in the Wnt pathway, whereas the synthetic molecules of Group VI function to stimulate the activity of a legless protein.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. For example, the protein of Group II functions as a legless protein in the Wnt pathway, whereas the antagonists of Group VIII function to decrease the activity of a legless protein.

Inventions II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in a method of treatment for a cell fate disorder, which is materially different than the method of screening of Group IX.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in a method of screening for legless antagonists, which is materially different than the method of treatment of Group X.

Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in a method of screening for legless antagonists, which is materially different than the method of diagnosis of Group XI.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different functions and different effects. For example, the methods of Group III have the effect of isolating a legless binding protein, whereas the methods of Group IV have the effect of making a legless protein.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used in a method of diagnosis by determining the level of a legless protein, which is materially different than the method of isolating a legless binding protein of Group III.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the compound of Group VI functions to interfere with the binding of a protein binding partner to a legless protein.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the compound of Group VII functions to stimulate the activity of a legless protein.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the antagonist of Group VIII functions to inhibit the activity of a legless protein.

Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the methods of Group IX function to determine an antagonist of a legless protein.

Inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the methods of Group X function to treat a subject with a disease.

Inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the methods of Group XI function to diagnosis a subject with a cell fate disorder.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used in a method of diagnosis by determining the level of a legless protein, which is materially different than the method of making a legless protein of Group IV.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group III function to isolate a legless binding protein, whereas the compound of Group VI functions to interfere with the binding of a protein binding partner to a legless protein.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group IV function to make a legless protein, whereas the compound of Group VII functions to stimulate the activity of a legless protein.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group IV function to make a legless protein, whereas the antagonist of Group VIII functions to inhibit the activity of a legless protein.

Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group IV function to make a legless binding protein, whereas the methods of Group IX function to determine an antagonist of a legless protein.

Inventions IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group IV function to make a legless protein, whereas the methods of Group X function to treat a subject with a disease.

Inventions IV and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the methods of Group IV function to make a legless protein, whereas the methods of Group XI function to diagnosis a subject with a cell fate disorder.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation. For example, the antibody of Group V operates by binding to a legless protein and increasing its rate of degradation, whereas the compound of Group VI operates by interfering with the binding of a binding partner to a legless protein.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation. For example, the antibody of Group V operates by binding to a legless protein and increasing its rate of degradation, whereas the compound of Group VII operates by stimulating the activity of a legless protein.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation. For example, the antibody of Group V operates by binding to a legless protein and increasing its rate of degradation, whereas the compound of Group VIII operates by antagonizing the activity of a legless protein.

Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used in a method of diagnosis wherein the level of a legless protein is determined, which is materially different than the method of screening antagonists of Group IX.

Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used in a method of diagnosis wherein the level of a legless protein is determined, which is materially different than the method of treatment of Group X.

Inventions V and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used in a method of treatment for a cell fate disorder, which is materially different than the method of diagnosis of Group XI.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different effects. For example, the compound of Group VI has the effect of interfering with the binding of a legless partner with a legless protein, whereas the compound of Group VII has the effect of stimulating the activity of a legless protein.

Inventions VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation. For example, the compound of Group VI operates by interfering with the binding of a legless partner with a legless protein, whereas the compound of Group VIII operates by antagonizing the activity of a legless protein.

Inventions VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group VI can be used in a method of treatment for a cell fate disorder, which is materially different than the method of screening antagonists of Group IX.

Inventions VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group VI can be used in a method screening for legless antagonists, which is materially different than the method of treatment of Group X.

Inventions VI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the compound of Group VI functions to interfere with the binding of a binding partner of a legless protein, whereas the method of Group XI functions to diagnose a subject with a cell fate disorder.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different effects. For example, the synthetic molecule of Group VII has the effect of stimulating the activity of a legless protein, whereas the molecule of Group VIII has the effect of antagonizing the activity of a legless protein.

Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the synthetic molecule of Group VII can be used in a method of treatment, which is materially different than the method of screening of Group IX.

Inventions VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the synthetic molecule of Group VII can be used in an in vitro legless assay, which is materially different than the method of treatment of Group X.

Inventions VII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the synthetic molecule of Group VII can be used in a method of treatment, which is materially different than the method of diagnosis of Group XI.

Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist of Group VIII can be used in a method of treatment, which is materially different than the method of screening of Group IX.

Inventions VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist of Group VIII can be used in a method of screening antagonists, which is materially different than the method of treatment of Group X.

Inventions VIII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the compound of Group VIII functions to antagonize the activity of a legless protein, whereas the method of Group XI functions to diagnose a cell fate disorder in a subject.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the method of screening of Group IX has the effect of determining an antagonist of a legless protein, whereas the method of Group X has the effect of treating a disorder in a subject.

Inventions IX and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the method of screening of Group IX has the effect of determining an antagonist of a legless protein, whereas the method of Group XI has the effect of diagnosing a cell fate disorder in a subject.

Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. For example, the method of treatment of Group X has the effect of treating a subject for a disorder, whereas the method of Group XI has the effect of diagnosing a cell fate disorder in a subject.

Sequence Election Requirement Applicable to All Groups

In addition, Groups I-XI detailed above read on patentably distinct complex sequences. For example, Group I and IV and X and XI read on a nucleic acid of SEQ ID NO: 1 or 16. Groups II, III, V, VI, VII, VIII, IX, XI read on a polypeptide encoded by SEQ ID NO: 1 or 16 or homology domains of SEQ ID NO: 2, 3, 4 or 5. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For each of Groups I-IX, the Applicants must further elect a

Art Unit: 1635

single sequence for examination (either **one** nucleotide sequence or a polypeptide encoded by **one** nucleotide sequence or **one** homology domain, as appropriate to the elected Group). (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

It has been decided that, due to the high burden placed on the Office to search sequences, **ONE** sequence constitutes a reasonable number for examination purposes. Applicant is required to elect **ONE** independent and distinct sequence. Examination will be restricted to only the **ONE** elected sequence.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


KAREN LACOURCIERE
PATENT EXAMINER

Karen A. Lacourciere
September 18, 2002